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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/522,457	01/21/2005	Eric Ferrandis	427.094	5578

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EXAMINER	
GUSSOW, ANNE	
ART UNIT	PAPER NUMBER
1643	

DATE MAILED: 10/13/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/522,457	FERRANDIS ET AL.	
	Examiner	Art Unit	
	Anne M. Gussow	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 2-6 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 2-6 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on 1/21/05 is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 1/21/05.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim 1 is cancelled.

Claims 2-6 are pending and are under examination.

Specification

1. The amendment filed 1/21/05 has been entered.

2. The use of the trademark SEPHADEX®, for example, has been noted in this application. Trademarks should be capitalized wherever they appear and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Examiner has given cursory review for use of trademarks; applicant is requested to correct the use of trademarks throughout.

Abstract

3. Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

In the instant case, the examiner is objecting to the improper use of the word said in the abstract. Please re-write the abstract on a separate page with the US serial number.

Claim Rejections - 35 USC § 112

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

5. Claims 2-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite in the description of the 90 kD protein. In consideration of the discrepancies often encountered in the art between protein molecular weight when determined by different methods, when a molecular weight is recited to characterize a protein the claims should include not only the method by which it was determined, e.g. whether by sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration or some other method, but also whether the determination was made under denaturing or non-denaturing conditions and whether reducing or non-reducing conditions were used.

6. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claims 2-6 are rejected under 35 U.S.C. 112, first paragraph, because the specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to use the invention.

Factors to be considered in determining whether a disclosure meets the enablement requirement of 35 USC 1 12, first paragraph, have been described by the court in In re Wands, 8 USPQ2d 1400 (CA FC 1988).

Wands states on page 1404,
"Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized by the board in Ex parte Forman. They include (1) the quantity of experimentation necessary, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims."

The claims are broadly drawn to a method of using a 90 kD protein (here forth designated Heterocarpine) isolated from the plant Pilocarpus heterophyllus, comprising fragments of peptide sequences SEQ ID Nos: 1, 2, and 3. The claims are broadly drawn to treating just any cancer or lung and breast cancer dependent on growth factor GHRH with said protein.

The specification discloses treating rats with an intravenous injection of increasing doses of heterocarpine and measuring growth hormone levels in blood samples. The specification also discloses injection of heterocarpine in increasing doses to mice having a tumor xenograft of small-cell lung cancer cells, however, the relevant experimental data for treating cancer was not provided. The specification does not disclose similar treatment of breast cancer tumors with heterocarpine. The specification

does not enable any method of treatment of any cancer by administration of heterocarpine.

Cancer treatment with peptides is probably one of the most unpredictable areas of biotechnology. For example, Ezzat, et al. (Cancer Vol. 71 No. 1 pp. 66-70 1993, particularly, figure 3) teach that administering the cyclic octapeptide Octreotide to a patient with metastatic pancreatic tumor up to 1500 μg/day was clinically, biochemically, and radiographically ineffective over the course of the 3 day study. Longer-range treatment of pituitary tumors with either octreotide or another peptide analog, lanreotide, resulted in considerable variability as taught by Freda (Journal of Clinical Endocrinology and Metabolism Vol. 87 No. 7 pp. 3013-3018 2002, particularly, tables 1 and 2) in both tumor shrinkage and suppression of GH levels. Additionally, treatment of pituitary tumors with a synthetic peptide GH-releasing peptide had mixed results as taught by Alster, et al. (Journal of Clinical Endocrinology and Metabolism Vol. 77 No. 3 pp. 842-845 1993, particularly figure 1). In this study the GH responses to GHRP and GHRH were not correlated, while the responses to GHRP and TRH were highly correlated. Taken together, these results suggest that although GH release is being stimulated by administration of each of the peptides, the individual response related to the tumor is unpredictable.

Since the specification provides no guidance as to the result of treating a GHRH dependent tumor with heterocarpine, undue experimentation would be required to determine if this treatment would be effective. Therefore, in considering factors in determining whether undue experimentation is required, as summarized in In re Wands,

8 USPQ2d 1400 (CA FC 1988), which include the nature of the invention, the state of the prior art, the relative skill of those in the art, the amount of direction or guidance disclosed in the specification, the presence or absence of working examples, the predictability or unpredictability of the art, the breadth of the claims, and the quantity of experimentation which would be required in order to practice the invention as claimed, one of skill in the art would be required to perform undue experimentation to use the heterocarpine protein to treat cancer as broadly claimed.

Conclusion

8. No claims are allowed.

Claims 2-6 are free of the prior art. The closest prior art is Jaffe, et al. (Journal of Clinical Endocrinology and Metabolism Vol. 82 No. 2 pp. 634-637, 1997). Jaffe et al. teach on the use of GHRH antagonists to suppress growth hormone in patients with GHRH-secreting carcinoid tumors. Administration of GHRH antagonist suppressed GH hypersecretion over the 5-day course of the study, however, Jaffe et al. does not teach on the long-term effects of GHRH antagonists on tumors. Jaffe et al. does not teach or fairly suggest the use of a 90.0 kD protein isolated from *Pilocarpus Heterophyllus* to treat cancer.

9. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne M. Gussow whose telephone number is (571) 272-6047. The examiner can normally be reached on Monday - Friday 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms can be reached on (571) 272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER